OCT 9 2012

510(k) Summary, K112837

Sponsor	Vilex in Tennessee, Inc., 111 Moffitt St., McMinnville, TN 37110, Phone: 931-474-7550, Fax: 931-474-7551, Email: sylvias@vilex.com
Contact	Sylvia Southard
Date	September 27, 2012
Device Name	Vilex eZ-Staple Superelastic Bone Fixation Staple
Classification	21 CFR 888.3030 – Single/multiple component metallic bone fixation appliances and accessories Product Code: JDR Regulatory Class: II
Predicate Devices	Memometal Technologies' Memometal Memory Staples - K070031 - (Trade name: MMI EasyClip® SI)
Description of Device	The Vilex eZ-Staple Superelastic Bone Fixation Staple is a single-use bone fixation appliance intended to be permanently implanted. Super Elastic staples are compression staples made of shape memory nickel titanium alloy, Nitinol. Vilex will offer Monocortical Staples ranging in width from 10mm to 20mm with leg lengths ranging from 10mm to 20mm and Biocortical Staples ranging in width from 10mm to 18mm with leg lengths from 15x13 to 19x17.
Material	Titanium-Nickel alloy, Nitinol, for human implanting. ASTM F2063-05 Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants
Indications for Use	The Vilex eZ-Staple (Superelastic Bone Fixation Staple) is indicated for hand and foot bone fragments osteotomy fixation and joint arthrodesis.
Non-Clinical Test Data	Samples of the Vilex eZ-Staple have been tested according to ISO 10993 and applicable FDA regulations for: • Cytotoxicity (MEM Elution) • Genotoxicity (Ames Assay) • Intracutaneous Reactivity • Acute Systemic Toxicity • Material-Mediated Pyrogenicity Additionally, samples of the Vilex eZ-Staple have also been tested to relevant ASTM standards versus samples of the predicate device for: • Corrosion Susceptibility • Auger Electron Spectroscopy of Oxide Layer • Pullout Strength • Static Bending Stiffness • Dynamic Bending Fatigue Life
Substantial Equivalence	Documentation is provided which demonstrates that the Vilex eZ-Staple is substantially equivalent to other legally marketed devices in terms of intended use and indications for use, material, design and function. Any minor differences between these two devices do not raise new questions of safety and effectiveness.
Establishment Reg. No.	1051526

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

OCT 9 2012

Vilex, Inc.
% Ms. Sylvia Southard
111 Moffitt Street
McMinnville, Tennessee 37110

Re: K112837
Trade/Device Name: Vilex eZ-Staple (Memory Bone Fixation Staple)
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: JDR
Dated: September 27, 2012
Received: September 28, 2012

Dear Ms. Southard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K112837

Device Name: Vilex eZ-Staple (memory bone fixation staple).

Indications for Use:

The Vilex memory bone fixation staples (eZ-Staple) are indicated for hand and foot bone fragments osteotomy fixation and joint arthrodesis.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112837